TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE

FISCAL MEMORANDUM

SB 676 – HB 1264

April 10, 2013

SUMMARY OF ORIGINAL BILL: Requires the Board of Pharmacy and any appropriate occupation or professional licensing board, which may legally dispense controlled substances, on or before October 1, 2013, to promulgate rules that:

- create standards of care for all prescribers and dispensers of controlled substances for treatment of chronic pain, including adoption of protocols for diagnosis and treatment;
- establish restrictions on prescriptions of controlled substances in regards to quantities and combinations, as appropriate;
- establish protocols for notification of law enforcement when abuse of controlled substances or violation of laws regarding prescribing, dispensing or possessing controlled substances is suspected, within the limitations of state and federal privacy laws and regulations; and
- develop standards for analyzing data in the controlled substances database to identify patterns of prescription drug prescribing and dispensing that raise a reasonable likelihood of improper or illegal prescribing, dispensing, or diversion in consultation with the Tennessee Bureau of Investigation (TBI).

Requires any person applying to hold the right to dispense controlled substances to annually complete at least eight hours of annual pain management training, which must include medicine addiction education, guidelines for prescribing, risk management tools, and other pertinent information for the safe prescribing and dispensing of narcotics. Authorizes dispensation of any Schedule II or III controlled substance in emergency situations by oral prescription by a practitioner and reduced promptly to writing and filing by the dispensing pharmacy. Creates various provisions to effectuate this emergency dispensation. Requires any patient, who is prescribed a Schedule II or III controlled substance for a period greater than 30 days, to undergo urine drug testing upon initial assessment and no less than once every 30 days. Requires the Board of Pharmacy to promulgate rules and regulations to effectuate this.

Broadens the definition of a "pain management clinic" to mean any privately owned clinic, facility, or office which advertises for any type of pain management services, or employs a practitioner who is primarily engaged in the treatment of pain. Requires patients of a pain management clinic to have current and valid government issued identification; be referred to the clinic from a primary care physician or other licensed physician treating the patient for the conditions underlying the patient's chronic pain; and submit to urine drug screening in accordance with a written drug screening policy and compliance plan. Requires patient records to include current MRI, X-ray, CT scan or other diagnostic testing to demonstrate a basis for prescribing of a controlled substance.

CORRECTED FISCAL IMPACT OF ORIGINAL BILL:

Increase State Expenditures - $45,996,700/FY13-14
$61,328,900/FY14-15 and Subsequent Years

Increase Federal Expenditures - $85,121,300/FY13-14
$113,495,000/FY14-15 and Subsequent Years

Increase Local Expenditures - $68,600/FY13-14*
$91,500/FY14-15 and Subsequent Years

SUMMARY OF AMENDMENTS (006717, 005789): Deletes all language after the enacting clause. Requires the Commissioner of the Department of Health, by January 1, 2014, to develop recommended treatment guidelines for prescribing opioids, benzodiazepines, barbiturates, and carisoprodol that can be used by prescribers in the state as a guide for caring for patients. Further requires the Commissioner to review and update the such guidelines by September 30th of each year, and post such updates on the Department's website. Guidelines shall be sent to the appropriate licensing boards and such boards are required to review them and determine how they may be used for their licensees. Requires, on or after July 1, 2014, all prescribers holding a Federal Drug Enforcement Administration (DEA) license and who prescribe controlled substances, to biennially complete a minimum two hours of continuing education related to controlled substance prescribing which will count towards the licensee's mandatory continuing education. These provisions do not apply to veterinarians, providers practicing at a registered pain management clinic, or to medical doctors or osteopathic physicians board certified by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) in one or more of the following specialties or subspecialties: pain management, anesthesiology, physical medicine and rehabilitation, or neurology.

Prohibits any Schedule II, III, or IV controlled substance from being prescribed in quantities greater than a 30-day supply. Prohibits a pain management clinic from prescribing opioids, benzodiazepines, barbiturates, or carisoprodol. Requires any prescriber who prescribes opioids, benzodiazepines, barbiturates, or carisoprodol to submit the transaction to the controlled substance monitoring database. Requires any prescriber who prescribes opioids, benzodiazepines, barbiturates or carisoprodol, either alone, concurrently, or sequentially with any other opioids, benzodiazepines, barbiturates, or carisoprodol to patients who are being administered chronic, long-term drug therapy for ninety days or longer must consider mandatory urine drug testing.

Requires wholesalers and manufacturers that sell controlled substances at wholesale provide the following information to the Automation of Reports and Consolidated Orders System (ARCOS):

- DEA registration number, or other mutually acceptable identifier
- Purchaser's DEA registration number, or other mutually acceptable identifier
- National drug code number of the actual drug sold
- Quantity of the drug sold
- Date of sale

- Transaction identifier or invoice number

Requires that the Commissioner of Health, in consultation with the Board of Medical Examiners, the Board of Osteopathic Examination, the Board of Nursing, and the Committee on Physician Assistants, promulgate rules requiring pain management clinics to require patients to carry current and valid government-issued identification or a current health insurance card issued by either a government or private carrier and further requires that providers consider urine drug screening in accordance with a written drug screening and compliance plan, which may include testing on initial assessment or upon new admission. Limits the involvement of a medical doctor to four pain management clinics. Prohibits pain management clinics from receiving payment in the form of a money order. Increases the administrative penalty, from $1,000 per day to at least $1,000, but not to exceed $5,000 per day, for any practitioner who provides pain management services at an uncertified pain management clinic. Defines "healthcare practitioner extender" and states that a prescriber has the ability to authorize a healthcare practitioner extender to check the controlled substances database for other prescribers in the authorizing prescriber's practice. Further states that any one-time costs required to be made to effectuate the provisions of this act specific to system modifications will be shared on a pro-rata basis by the appropriate prescribing boards, excluding the Board of Pharmacy.

By January 31st of each year, the Commissioner of Health and each appropriate licensing board are required to prepare a comprehensive report on actions relative to prescription drug abuse and pain management clinics to the General Assembly for action in the prior calendar year. The report must summarize the number of complaints received, frequent findings, and actions taken.

Amendment 6717 replaces "Schedule II-IV controlled substance" with "any opioids, benzodiazepines, barbiturates, or carisoprodol."

FISCAL IMPACT OF BILL WITH PROPOSED AMENDMENT:

Increase State Expenditures - $26,600/FY13-14
$35,400/FY14-15 and Subsequent Years

Other Fiscal Impact – This increase in state expenditures will be charged to the licensing boards that currently support the Controlled Substance Monitoring Database. Such increase can be covered by the cumulative reserve balances of the board most impacted. As of June 30, 2012, the cumulative reserve balances for the boards most impacted was $6,706,200.

Assumptions for the bill as amended:

- According to the Department of Finance and Administration, Division of Benefits Administration, there will be no significant impact on insurance claims made by any member of the state plan, local education, or local government plan.
- According to the Bureau of TennCare, there will be no significant fiscal impact on the Bureau as a result of this bill.

- According to the Department of Health, there will be an increase in state expenditures to create and maintain the system to receive and store the data from wholesalers in ARCOS format to the Controlled Substance Monitoring Database (CSMD).
- There are currently approximately 105 wholesaler and manufacturers licensees under the Board of Pharmacy who will be required to report to ARCOS.
- According to an ARCOS estimate, it will cost approximately $5 per user (licensee) per month to receive and store this data in ARCOS format, resulting in an increase in recurring state expenditures of $6,300 (105 x $5 x 12 months).
- There will be database storage costs of $30.50 per month, resulting in an increase in recurring state expenditures of $366 ($30.50 x 12 months).
- It will take an existing database administrator position a total of 104 additional hours annually at $35.54 per hour to handle this additional data, resulting in an increase in recurring state expenditures of $1,244 ($35.54 x 35 hours).
- According to the Department of Health and the current vendor who maintains the CSMD, it is estimated that providing the prescriber the option to allow the healthcare practitioner access to the CSMD will result in an increase in state expenditures of $27,500.
- The total estimated recurring increase in state expenditures is estimated to be $35,410 ($6,300 + $366 + $1,244 + $27,500).
- This bill has an effective date of October 1, 2013, which will result in 75 percent of annual expenditures being realized in FY13-14.
- In FY 13-14, there will be an increase in state expenditures of $26,558 ($35,410 x 0.75).
- In FY 14 -15 and subsequent years, there will be an increase in state expenditures of $35,410.
- This increase in state expenditures will be charged to the appropriate licensing boards which currently support the CSMD.
- Pursuant to Tenn. Code Ann. §4-3-1011, all regulatory boards are required to be self-supporting over a two-year period. The Board of Pharmacy had closing balances of $553,901 in FY10-11, $85,209 in FY11-12, and a closing reserve balance of $929,407 on June 30, 2012.
- The Board of Medical Examiners had closing balances of $613,808 in FY10-11, $687,808 in FY11-12, and a closing reserve balance of $2,153,016 on June 30, 2012.
- The Board of Osteopathic Examination had closing balances of $132,030 in FY10-11, $117,644 in FY11-12, and a closing reserve balance of $345,204 on June 30, 2012.
- The Board of Nursing had closing balances of $1,720,424 in FY10-11, $1,277,018 in FY11-12, and a closing reserve balance of $3,278,591 on June 30, 2012.

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.

Lucian D. Geise, Executive Director

/jdb